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C O N F I D E N T I A L SANTO DOMINGO 001335

SIPDIS

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TAGS: ETRD EINV PREL DR
SUBJECT: Pharma Industry Laments Lack of Patent Protection

CLASSIFIED BY: Alexander H. Margulies, PolEcon Counselor, DOS, Ecopol; REASON: 1.4(B), (D)

¶1. (SBU) SUMMARY: The Dominican Republic has serious gaps in its legal and regulatory structure concerning pharmaceutical products. The patent-issuing authority, ONAPI, has not issued any new pharmaceutical patents this year, has a backlog of over 700 cases, and has cases that have been pending since 2001. The government entity in charge of approving pharmaceutical products for sale, SESPAS, has no legal mandate to ensure that patents are being upheld and, even if it were to have such a mandate, no official patent registry exists for it to check. Moreover, the illegal copying of a patented product is a civil, not criminal, offense with minor penalties attached to violations. The government will need to take several steps in a number of areas to bring the process to the standards that comply with the spirit - if not the letter - of DR-CAFTA, but has demonstrated little interest in doing so and faces considerable opposition to reform from the domestic drug-pirating industry. END SUMMARY.

PHARMA LAYS OUT ITS PROBLEMS

¶2. (SBU) On December 2, the ChargC), PolEcon Counselor, and EconChief met with a delegation of pharmaceutical industry representatives who were calling on Government of the Dominican Republic (GoDR) officials to address problems in the patent-approval process. The delegation included: PhRMA (the Pharmaceutical Research and Manufacturers of America), Fedefarma (FederaciC3n Centroamericana de Laboratorios FarmacC)uticos), Novartis, and Merck as well as Mary FernC!ndez Rodriguez, the group's local counsel.

¶3. (SBU) The meeting began with the Novartis representative observing that the DR was a critical market for the pharmaceutical industry, not necessarily in proportion to its market share but due to its important role as a Free Trade Agreement (FTA) partner of the United States. The industry would like to use successful cooperation with the DR as an example to encourage other countries throughout Latin America to follow its lead (and not the lead of the "Venezuelas and Bolivias"). However, the DR has yet to provide a good story to tell: of the 700-plus patent requests lodged to date by the pharmaceutical industry, only ten to 15 have been approved in the last decade and none has been approved this year. The process is complicated by both a Dominican Supreme Court ruling and a law passed in 2000 that ban "confirmation patents." These patents would allow ONAPI (Oficina Nacional de la Propriedad Industrial), the country's patent issuing authority, to use patents issued by other countries as the basis for its decision. Without authority to recognize confirmation patents, ONAPI must fully

assess each request it receives rather than using work done by external authorities with greater expertise.

TECHNICAL LIMITATIONS: LACK OF RESOURCES UNDERMINES TRAINING

¶4. (SBU) The group expressed the common sentiment that ONAPI was committed to improving the patent-issuing process, but significant amounts of technical assistance would be needed to get its staff to the required level of competence. (COMMENT: Moreover, ONAPI is hamstrung by a more general lack of resources. According to USAID's DR-CAFTA implementation team, ONAPI currently has only six patent examiners, and only one of them focuses on pharmaceuticals. It is hoping to hire six more, two of whom would focus on pharmaceuticals. END COMMENT.) The group voiced support for the new head of ONAPI - who has been in place four months - but noted his surprise when he learned that some patent requests have been pending since 2001. (COMMENT: The group informed us that the average wait time for a patent request in the U.S. is three years; in Guatemala - one of the countries lauded by the group for its efforts - it takes three to four years, while in Argentina it takes seven to eight years. END COMMENT.) The industry highlighted the cooperation it enjoys from the Secretary of State of Public Health and Social Assistance (the SecretarC-a de Estado de Salud PC:blica y Asistencia Social), or SESPAS, the GoDR agency responsible for maintaining the sanitary registry, on which a pharmaceutical product must appear to be sold in the local market.

"NOT ONLY UNHELPFUL BUT DETRIMENTAL:" LEGAL AND POLITICAL HURDLES

¶5. (C) The group was unequivocal in pointing the finger of blame

for the paralysis in patent-issuing process at Yahaira Sosa Machado, the head of the Industry & Commerce Ministry's Directorate of External Commerce and Trade Agreement Administration (la DirecciC3n de Comercio Exterior y AdministraciC3n de Tratados Comerciales Internacionales), or DICOEX. According to FernC!ndez, Sosa - who, as head of DICOEX, has primary responsibility for DR-CAFTA implementation - told the group that she will implement the letter, and no more, of that Agreement and implementing laws and regulations. Although ONAPI is the DR's patent-issuing agency, FernC!ndez is convinced that Sosa is somehow holding up the process. As proof of Sosa's obstructionist role, FernC!ndez highlighted comments made by the head of SESPAS that DICOEX was blocking many of its attempts to work with the industry. The PhRMA representative noted that it was pursuing projects with SESPAS that did not require the expenditure of Dominican Government resources in order to get around DICOEX.

¶6. (SBU) In response to these comments, PolEcon Counselor and EconChief met with members of USAID's DR-CAFTA implementation team to get its assessment of the situation. Although the team agreed that DICOEX was not going to go beyond the letter of the law, it observed that the DR was technically in compliance with its DR-CAFTA requirements. The problems came not from the failure of DICOEX to implement the law, but from gaps in the laws and regulations that weakened cooperation between ONAPI and SESPAS. In theory, a pharmaceutical company would lodge its patent application with ONAPI and, if issued, ONAPI would notify SESPAS, which would in turn enforce the patent by ensuring that no new pharmaceutical products entered the sanitary registry if they violated an existing patent. However, the team explained that not only is ONAPI not issuing patents, but a patent registry does not, at this point, exist. Moreover, even if a patent registry did exist, SESPAS is not legally required to check it before registering a new product. Instead, under current law, a company need only file a notarized letter ("declaraciC3n jurada") stating that its product does not violate any patents, and SESPAS uses this statement as sufficient evidence to register the product. (COMMENT: This disconnect - both in the absence of a formal patent registry as well as SESPAS' failure to check it - supports the perception of the pharmaceutical representatives that the DR is observing the letter, but not the spirit, of DR-CAFTA. END COMMENT.)

COPYING AND COUNTERFEITING: ON THE GROUND REALITIES

¶7. (SBU) The industry representatives lamented their difficulties in contending with the powerful influence of the "copying" industry, which opposes any efforts to close the gaps in the law

and regulations that it currently exploits. They also complained that copying pharmaceuticals is a civil, not a criminal, offense in the DR. As such, copiers are unlikely to alter their behavior, given that civil cases often take seven to eight years to reach the judgment phase, and the amounts given by the courts are relatively small, consisting of only three or so months of the copiers' profits. The industry has had more success in prosecuting counterfeiting, since it is a criminal offense, though such successes usually come only through filing private criminal complaints, thereby circumventing the public prosecutors, whom FernC!ndez describes as being completely untrained to handle such cases.

COMMENT

¶8. (SBU) In order for the patent and registration process to work the way the industry would like, the GoDR will need to take several steps. First, ONAPI's technical staff will need to receive training in order to assess the technical and scientific merits of patent application (and its members will need to remain in the office). Second, ONAPI will need to move through the backlog of cases and ensure that patents - both issued and pending - are included in a patent registry that it shares with SESPAS. Then, SESPAS will have to use this information in deciding which products to place on the sanitary registry. Finally, the GoDR will need to establish an enforcement mechanism - perhaps through the criminalization of patent violation - that will allow patent holders to file suit against patent violators. The GoDR, however, has demonstrated little interest in meeting the spirit, rather than

the letter, of patent protection under DR-CAFTA. Furthermore, any attempt to do so would encounter considerable opposition from the local drug-pirating industry, which, according to USAID's consultants, has a large role in formulating the existing patent regime.

¶9. (SBU) COMMENT CONTINUED: Embassy would welcome suggestions/seeks guidance from Department, USDOC, or USTR regarding ways to encourage the GoDR to address the shortcomings in its patent regime. In the meantime, USAID will continue working with ONAPI to improve the technical expertise of its staff. SESPAS has announced its intent to publish on its website applications for registration, allowing patent holders at least some insight into the process. However, barring significant diplomatic pressure from DR-CAFTA partners, it is unlikely that the patent-issuing process will improve in the near future. END COMMENT.
Lambert